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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,598	04/26/2001	H. Robert Horvitz	01997/S25002	8753

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EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,598

Applicant(s)

HORVITZ ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/14/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Applicant's amendment received on 10/14/03 has been entered. Claims 1-7 and 11-12 have been amended. New claims 13-22 have been added. Claims 1-22 are pending and are under current consideration.

Oath/Declaration

The substitute declaration received on 10/14/03 is complete and has been entered.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 2-5 of the Office action mailed on 4/9/03.

Applicant's arguments filed 10/14/03 have been fully considered but they are not persuasive. Applicants have argued that every species within a genus need not be described in order that a genus meets the written description requirement. Applicants assert that it may not be necessary to enumerate a plurality of species if a genus is

sufficiently identified. Applicants further assert that the instant specification teaches that the genus of nematodes recited in the present claims are derived from a single species, *C. elegans*, and that they express a CeSERT polypeptide deficient in serotonin reuptake activity. Applicants also point out the instant specification has described identification and cloning of the mod-5 gene, which encodes CeSERT. Applicants submit the instant specification has provided a correlation between the functional property of the CeSERT polypeptide (serotonin reuptake) with a structural property of the polypeptides (the transmembrane domain). See pages 8-13 of the amendment received on 10/14/03.

In response, the Examiner maintains the instant specification has only described *C. elegans* comprising a mutated mod-5 gene comprising mod-5 (n822), mod-5 (n823), or mod-5 (n3314) mutations. The Examiner further maintains the instant specification has failed to describe the other nematodes embraced by the claims. The skilled artisan cannot envision the detailed chemical structure of the encompassed nematodes, and therefore conception is not achieved until reduction to practice has occurred. Moreover, the specification has not described any other mutations in a mod-5 gene that affect serotonin uptake, in particular that reduce serotonin uptake. The evidence of record has not provided a correlation between other mod-5 mutations and reduced serotonin uptake. Furthermore, the evidence of record has not even contemplated, let alone described, species of nematodes other than *C. elegans* embraced by the instantly claimed invention. It is therefore maintained one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus of nematodes expressing a mutated CeSERT

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polypeptide, other than *C. elegans* having a mutated mod-5 polypeptide comprising mod-5 (n822), mod-5(n823), or mod-5(n3314) mutations.

Accordingly, the rejection is maintained for the reasons of record.

The amendment received on 10/14/03 has necessitated the following new grounds of rejection under 35 U.S.C. 112, first paragraph:

New Matter

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claim 1 (and claims 2-11 that depend therefrom) is directed to a method for determining the activity range of a test compound against a secondary target that is not a serotonin reuptake transporter (SERT).

The specification provides no implicit or explicit support for the context of test compounds that do not modulate the uptake of serotonin. The specification has only provided support for test compounds, which modulate the uptake of serotonin.

Applicants are reminded that it is their burden to show where the specification supports

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any amendments to the claims. See 37 CFR 1.121 (b)(2)(iii), the MPEP 714.02, 3rd paragraph, last sentence and also the MPEP 2163.07, last sentence.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure* [or point to case law supporting incorporation of such a limitation as in the instant case]".

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The previous rejection is maintained for the reasons of record advanced on pages 5-8 of the Office action mailed on 4/9/03.

Applicant's arguments filed 10/14/03 have been fully considered but they are not persuasive. Applicants argue the specification has provided several methods for identifying nematodes expressing a mutated CeSERT polypeptide with reduced serotonin uptake. Applicants further argue the specification has described uses of such nematodes, particularly for identifying test compounds that modulate serotonin reuptake by acting on a target other than CeSERT. See pages 14-17 of the amendment.

In response, the Examiner maintains the instant specification has provided guidance for use of *C. elegans* mutants mod-5 (n822), mod-5 (n823) or mod-5 (n3314) but the instant specification has failed to provide guidance for use of other nematodes embraced by the claims. While the instant specification has contemplated other nematodes may be used for practicing the claimed invention, it appears the instant specification has failed to recite which other nematodes could be used. It is further maintained a mere statement that other nematodes exist and could be used is not sufficient to enable the breadth of the methods as directed to any nematode expressing a mutated CeSERT polypeptide. If there is no disclosure of starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art. See *Genentech Inc. v. Novo Nordisk A/S* 42 USPQ2d 1001, 1997. In this case the starting material that has

not been disclosed is any other nematode expressing a CeSERT polypeptide embraced by the claims. See pages 6-7 of the Office action mailed on 4/9/03.

The aspect of the rejection relating to the mod-5 (n3314) mutant has been withdrawn in view of Applicant's arguments presented in the last paragraph of page 17.

Applicants argue the specification has taught several defined behaviors, which can be altered by modulating the activity of a non-CeSERT secondary target, altered by which can be examined in nematodes expressing a defective CeSERT polypeptide. Applicants submit the specification describes behaviors, such as locomotory rate in response to a food source and egg laying. See pages 18-20 of the amendment.

In response, the Examiner maintains the claims as written are broad as they encompass any defined behavior and any secondary target. The claims (1-22), as written, fail to provide a correlation between defined behaviors and serotonin. In addition, the claims (1-11) fail to provide a nexus between modulation of the secondary target and serotonin uptake. Such a nexus appears to be important as the role of the secondary target appears to promote serotonin uptake by circumventing the defective CeSERT. Finally, given the breadth of the claims directed to any nematode expressing a mutated CeSERT, it would appear that such nematode comprises wild-type SERTs in addition to the mutated CeSERT. To that end the mutated CeSERT is interpreted to be expressed from an exogenous CeSERT DNA sequence. Consistent with such reasoning and given the plain language of the claims, it would appear that the embraced nematodes comprise wild-type SERTs. Therefore, the uptake of serotonin is normal and unaffected by the expression of mutated CeSERT in the nematodes. More

importantly, due to the presence of wild-type SERTs there is no way of knowing if the test compound is affecting a wild-type SERT or a secondary target. Applicants are reminded the claims require modulation of a secondary target by a test compound. Given the language of the claims, the evidence of record has failed to provide guidance for distinguishing modulation of a SERT as opposed to a secondary target in the presence of a test compound. As such, the claims as written are not enabled.

Accordingly, the previous rejection is maintained for the reasons of record.

Applicant's amendment has necessitated the following new ground of rejection:

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite as written. The claim is directed to a method for determining the activity range of a test compound against a secondary target that is not a serotonin reuptake transporter (SERT). The steps of the method only result in indicating that a compound has a secondary target. It appears that the steps of the method have not met the goal of the preamble, as an activity range of a test compound was not determined. Therefore, the claim is indefinite. Claims 2-11 depend from claim 1.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time). The examiner is scheduled to move a new office, on 1/13/2004, having a new telephone number as follows: 571-272-0732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

**PETER PARAS
PATENT EXAMINER**

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A handwritten signature in cursive script that reads "Pete Paras".